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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Applicati	on No	Applicant(s)			
Office Action Summary							
		10/579,8		SHIMIZU ET AL.	Γ		
		Examine		Art Unit			
	The MAU INC DATE of this communicati	ROBERT		1626	ddrooo		
Period fo	The MAILING DATE of this communicati r Reply	on appears on the	cover sneet with the	correspondence ac	iaress		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
2a)⊠	Responsive to communication(s) filed or This action is <b>FINAL</b> . 2b) Since this application is in condition for a closed in accordance with the practice u	This action is rallowance except	_ non-final. for formal matters, pr		e merits is		
Dispositi	on of Claims						
5)□ 6)⊠ 7)□ 8)□ <b>Applicati</b> 9)□	Claim(s) 1-3 is/are pending in the applicated Aa) Of the above claim(s) is/are work Claim(s) is/are allowed.  Claim(s) 1-3 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction  on Papers  The specification is objected to by the Ex  The drawing(s) filed on is/are: a)[  Applicant may not request that any objection	and/or election raminer. accepted or b) to the drawing(s) t	equirement. □ objected to by the be held in abeyance. Se	ee 37 CFR 1.85(a).	<b>FD 4 424(4)</b>		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
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Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
2)  Notic 3) Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-9 nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	148)	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal D 6) Other:	Date			

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#### **DETAILED ACTION**

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**Status of the claims**: Claims 1-3 are currently pending.

**Priority:** This application is a 371 of PCT/JP04/19474 (12/17/2004) and claims foreign priority to JAPAN 2003-420885 (12/18/2003).

#### Election/Restrictions

Applicant previously elected Group I:

Group I, claim(s) 1-3, drawn to a filter product of formula Ia:

$$R^{5}$$
  $R^{4}$   $R^{3}$   $Q^{-}$   $R^{10}$   $(R^{9})_{n}$  (Ia)

Applicant also elected the following species:

As was detailed in the requirement for restriction/election and stated in the prior office action, because the generic claim was not found patentable, the claims are restricted to the elected species only and the subject matter outside of the elected species held withdrawn.

## RESPONSE TO APPLICANT REMARKS

### Claim Rejections - 35 USC § 102

1. Claims 1-2 were rejected under 35 U.S.C. 102(b) as being anticipated by US 6599605.

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The prior art teaches the following compound:

. Applicant amended the claims to require the

R10 substitution on the connecting amino group to be other than hydrogen. Therefore the rejection is **withdrawn**.

#### **NEW CLAIM REJECTIONS**

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 2 are rejected under 35 USC 112 1<sup>st</sup> paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

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Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (ie. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to

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compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3<sup>rd</sup> column, 3<sup>rd</sup> paragraph). Below is such comparison.

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It is noted that in the following the comparison is focused on products and not method of use. It is to be understood, however, that a *prima facie* conclusion of lack of written description for product implies the same conclusion for the process of use. In other words, the process of use cannot be practiced in absence of the product.

## I. Scope of Claims (based on elected subject matter)

Compounds of Formula la:

$$R^{5}$$
  $R^{4}$   $R^{3}$   $Q^{-}$   $R^{10}$   $(R^{9})_{n}$  (Ia)

wherein R10 is an alkyl group optionally having substituents.

## II. Scope of Disclosure

#### Reduction to Practice:

The specification has not reduced any compounds of the formula la to practice.

#### Reduction to Structural or Chemical Formulas:

The only disclosure, in addition to the species reduced to practice, is in form of a <u>list</u> of possible substituents for each variable. This type of disclosure is not viewed to be a representation of any of the species it entails. A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there

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is no disclosure of species (eg. by reduction to structural/chemical formulas) in addition to those reduced to practice.

### III. Analysis of Fulfillment of Written Description Requirement:

(i) Substantial structural variation exists in the genus/subgenus embraced by claims 1-2; (ii) there is no disclosure of species supporting genus. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Because the applicant has amended the claims to a new subgenus that is not supported by any species and is not supported by the original disclosure, it is not compliant with the requirements of 35 U.S.C. 112. Therefore, the claims are rejected.

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses claim language referring to "substituent(s)" without clearly defining the metes and bounds of the term. In addition, one of ordinary skill in the art would not know how to construe the claims in order to determine whether they were, in fact, practicing the invention. For example, without a precise definition in the claims of what is meant by a substituent, a substituent group could be further substituted *ad infinitum* or could have an infinite number of alternatives.
- 7. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for an infinite scope of

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"substituents." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In <u>In re Wands</u>, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

- 1. The nature of the invention,
- 2. The state of the prior art,
- 3. The predictability or lack thereof in the art,
- 4. The amount of direction or guidance present,
- 5. The presence or absence of working examples,
- 6. The breadth of the claims,
- 7. The quantity of experimentation needed, and
- 8. The level of the skill in the art.

#### The nature of the invention

The nature of the invention is compounds of Formula la and various substituents thereof.

#### The state of the prior art and the predictability or lack thereof in the art

The synthesis of chemical compounds can be highly unpredictable for an infinite scope of compounds because of the possibility for side reactions, stability, etc.

# The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance as to how the entire scope of the claims can be practiced.

#### The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any substituent.

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## The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the art is high, it would require undue experimentation of one of ordinary skill in the art to prepare any substituent as instantly claimed since there is a significant amount of uncertainty as to whether side reactions will occur. whether the resulting compound will be stable, or even whether the compound will have the stated utility. Therefore, the claims lack enablement for substituents.

This rejection can be overcome by appropriately deleting all instances of "substituent(s)."

#### Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (WO 01/44375 (in Japanese), equivalent to US 6599605, all references are to the '605 patent) in view of Bloor (Can. J. Chem., v. 39 (1961), p. 2256-2261) and Davis et al. (Int. J. Quant. Chem., v. 72: p. 463-471, 1999).

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The instant claims are for a filter display device comprising a compound of the formula:

1. Determining the scope and contents of the prior art.

The Shimizu teaches the following compound:

useful for its light absorbing properties

resulting from the conjugated electronic system. Furthermore, the reference teaches how the absorption wavelength of the compounds can be fine tuned by altering the aromatic substituents (see col. 1, for example).

Bloor teaches how the electronic absorption properties of conjugated aromatic molecules can be predictably altered by changing substituent groups from amino to nitro.

Davis teaches how altering substituents on conjugated polymers can predictably alter the second-order optical properties of the conjugated systems. Specifically, the reference describes the "push-pull" effect of adding nitrophenyl and dimethylaminophenyl groups.

Ascertaining the differences between the prior art and the claims at issue.
 The difference between the prior art and the claims is the presence of a nitro group in the prior art.

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3. Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of conjugated organic molecules would be well versed in the teachings of references such as Bloor and Davis. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering the substituents on the conjugated molecules and screen them for absorption or other desirable optical properties.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

One of ordinary skill in the art would be motivated to fine tune the molecules taught by Shimizu and apply the principles taught by Davis and Bloor. Based on the teachings of Davis and Bloor, one of ordinary skill in the art would be motivated to alter the substituents on the phenyl group knowing that altering or removing the nitro group would have a predictable effect on the optical properties of the molecule.

In Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd., 87 USPQ2d 1452, 1454 (Fed. Cir. 2008), the Federal Circuit clarified the proof of obviousness in structural similarity situations such as this:

Where, as here, the patent at issue claims a chemical compound, the analysis of the third Graham factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art compounds. See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1377 [81 USPQ2d 1324] (Fed. Cir. 2006) (noting that, for a chemical compound, a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed compositions"

(quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc))). Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. See Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 [83 USPQ2d 1169] (Fed. Cir. 2007). In keeping with the flexible nature of the obviousness inquiry, KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 [82 USPQ2d 1385] (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301 [84 USPQ2d 1198] (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship ... to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Id. (quoting Dillon, 919 F.2d at 692).

In addition, the prior art compound shows a very close structural relationship to the claimed compound that one of ordinary skill in the art would conclude they have similar properties based on the knowledge and experience of those of ordinary skill in the art and the teachings of the prior art as a whole.

Therefore, the claim is rejected.

#### Conclusion

The claims are not in condition for allowance. The prior examination was confined to the elected species only and applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/ Examiner Art Unit 1626 /Kamal A Saeed./ Primary Examiner, Art Unit 1626